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Investor News

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Phase II Trial of Investigational Anetumab Ravtansine Does Not Meet Primary Endpoint in Second-Line Mesothelioma

Leverkusen, Germany, July 21, 2017 – Bayer today announced that a Phase II clinical trial evaluating its investigational oncology compound anetumab ravtansine (BAY 949343) as a monotherapy in patients with recurrent malignant pleural mesothelioma (MPM), who were previously treated, did not meet its primary endpoint of progression-free survival. The safety and tolerability of anetumab ravtansine were consistent with earlier clinical findings. Detailed study results are expected to be presented at an upcoming medical meeting.

“Malignant pleural mesothelioma is a very difficult-to-treat tumor, and we had hoped for a better outcome for patients,” said Robert LaCaze, Executive Vice President and Head of the Oncology Strategic Business Unit at Bayer. “We would like to thank the patients and their caregivers, as well as the study investigators for their participation and contributions in this study. Based on the available data, we remain committed to further evaluating the utility and safety of anetumab ravtansine across multiple tumor types with significant unmet medical need.”

Anetumab ravtansine is currently being investigated, as monotherapy and in combination, in additional studies, including a Phase Ib multi-indication study in six different types of advanced solid tumors, as well as a Phase Ib combination-study in patients with recurrent platinum-resistant ovarian cancer.

About the Phase II Study

The phase II clinical trial (NCT02610140) is a randomized, open-label, active-controlled, multicenter superiority study investigating anetumab ravtansine as second line treatment in patients with advanced or metastatic mesothelin-positive malignant pleural mesothelioma (MPM), whose disease had progressed after treatment with first-line platinum/pemetrexed-based chemotherapy. The trial randomized 248 patients in a

2:1 ratio to receive either anetumab ravtansine (6.5 mg/kg intravenously every three weeks) or vinorelbine (30 mg/m^2 intravenously every week).

The primary endpoint of the study was progression-free survival. Secondary endpoints included overall survival, as well as other indicators of efficacy, such as patient-reported outcomes, objective tumor response rate, duration of response, disease control rate, and durable response rate. Safety and tolerability of patients were also continuously monitored.

About Mesothelioma

Malignant pleural mesothelioma (MPM) is a rare and deadly cancer affecting more than 25,000 people globally, with about 3,000 new cases being diagnosed in the US and more than 12,000 in Europe each year. It is commonly caused by occupational or environmental exposure to asbestos. The majority of patients with MPM are not diagnosed until the disease has progressed to an advanced stage, with the onset of the disease in many cases occurring 20 to 40 years after exposure. Due to its aggressive nature, the estimated median overall survival is approximately one year from diagnosis. Rapid deterioration and poor survival are hallmarks of MPM. In first line therapy, cisplatin/pemetrexed has become the standard of care but nearly all MPM-patients progress during or after first-line treatment. In the second-line setting, the lack of an accepted standard of care treatment underscores the substantial unmet need in the treatment of MPM.

About Anetumab Ravtansine (BAY 949343)

Anetumab ravtansine is an antibody-drug conjugate (ADC) that specifically targets mesothelin, a surface marker protein overexpressed in many cancers. After binding to mesothelin, anetumab ravtansine is taken up inside the tumor cells, where degrading enzymes release cytotoxic DM4, a maytansinoid tubulin inhibitor, which induces cell cycle arrest and apoptosis in dividing cells.

In a Phase I clinical trial in patients with advanced solid tumors, anetumab ravtansine demonstrated promising efficacy with durable responses in patients with malignant pleural mesothelioma (MPM), and a manageable safety profile. In addition to the Phase II clinical trial in MPM, anetumab ravtansine is currently being investigated in a variety of other mesothelin-positive tumors, including a Phase Ib multi-indication study in six different types of advanced solid tumors (NCT03102320), as well as a Phase Ib

combination-study in patients with recurrent platinum-resistent ovarian cancer (NCT02751918).

Anetumab ravtansine is a compound developed by Bayer. In the development, the following collaborators were involved: The antibody was derived from the HuCAL technology platform of MorphoSys AG. In a 2008 license agreement with ImmunoGen, Inc., Bayer was granted exclusive rights for using their maytansinoid ADC technology to develop anti-tumor therapies targeting mesothelin. Both partners are entitled to milestone payments and royalties on commercial sales, if any.

About Oncology at Bayer
Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The oncology franchise at Bayer includes three oncology products and several other compounds in various stages of clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cancer is treated.

Bayer: Science For A Better Life
Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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